

Exhibit 1 to Response

New England Journal of Medicine

From Wikipedia, the free encyclopedia

The New England Journal of Medicine (*N Engl J Med* or **NEJM**) is an English-language peer-reviewed medical journal published by the Massachusetts Medical Society. It is one of the most popular and widely-read peer-reviewed general medical journals in the world. It is also the oldest continuously published medical journal in the world.

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The New England Journal of Medicine

Abbreviated title	N Engl J Med
Discipline	peer-reviewed medical journal
Language	English
Publication details	
Publisher	Massachusetts Medical Society (USA)
Publication history	founded 1812
Indexing	
ISSN	0028-4793 (http://worldcat.org/issn/0028-4793)
Links	
	<ul style="list-style-type: none">Journal homepage (http://www.nejm.org/)

History

The NEJM was founded by Dr. John Collins Warren in 1812 as a quarterly called *The New England Journal of Medicine and Surgery*. In 1828, it became a weekly, and was renamed *The Boston Medical and Surgical Journal*; one hundred years later, it took on its present name.

It publishes editorials, papers on original research, widely-cited review articles, correspondences, case reports, and has a special section called "Images in Clinical Medicine".

Authors have included Oliver Wendell Holmes, Sr., Hans Zinsser, and Lewis Thomas. One of its early editors, Jerome V. C. Smith, resigned in 1857 to assume his duties as mayor of the City of Boston.

Influence

The website for the George Polk Awards noted that its 1977 award to the *New England Journal of Medicine* "provided the first significant mainstream visibility for a publication that would achieve enormous attention and prestige in the ensuing decades"^[1]

The journal usually has the highest impact factor of the journals of clinical medicine (including the *Journal of the American Medical Association*, and *The Lancet*); in 2006, the impact factor was 51, according to Journal Citation Reports, the first research journal to break 50.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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Assistant Commissioner for Patents
Washington, D.C. 20231



On 7 May 2008

TOWNSEND and TOWNSEND and CREW LLP

By: Malinda Adogit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FitzGerald *et al.*

Application No.: 09/381,497

Filed: February 17, 2000

For: RECOMBINANT ANTIBODIES
AND IMMUNOCONJUGATES
TARGETED TO CD-22 BEARING
CELLS AND TUMORS

Confirmation No. 4036

Examiner: Parithosh K. Tungaturthi

Technology Center/Art Unit: 1643

DECLARATION OF DR. ROBERT J.
KREITMAN UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Dr. Robert J. Krietman, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.

2. I received in M.D. in 1985 from the Ohio State University. My internal residency training was at Duke University and my medical oncology fellowship training at the National Institutes of Health.

3. I currently hold the position of Chief, Clinical Immunotherapy Section, Laboratory of Molecular Biology, National Cancer Institute. I have been involved in research and developing immunotoxin agents for cancer therapy since 1989. I have participated as a investigator in over 10 clinical trials to investigate candidate therapeutic agents for the treatment of B-cell malignancies. A copy of by curriculum vitae is attached as Appendix A.

4. This Declaration is provided to attest to the fact that the level of efficacy that we observed in a phase I clinical trial using RFB4(ds)Fv-PE38 for the treatment of hairy cell leukemia (HCL) was unexpected.

5. RFB4(dsFv)-PE38 (referred to here as BL22) is a recombinant immunotoxin in which an RFB4 disulfide stabilized Fv fragment is joined to a truncated *Pseudomonas* exotoxin, PE38. The disulfide-stabilized Fv has a V_H with a cysteine residue at position 44 and a V_L with a cysteine residue at amino acid position 100. We first assessed the toxicity and activity of BL22 in 16 patients with purine-resistant HCL in a Phase I dose-escalation trial. The results demonstrated a high response rate: of the 16 HCL patients treated with the immunoconjugate, 11 achieved complete remissions and 2 achieved partial responses. The patients that achieved complete remission included three that had a poor-prognosis variant of HCL that responds poorly to any of the commonly used chemotherapeutic agents for HCL. These preliminary results were striking enough to warrant publication in the *New England Journal of Medicine* (*N Engl. J. Med* 345:242-247, 2001).

6. In total, 31 patients with hairy cell leukemia were evaluated in the phase I study. Of these patients, 19 (61%) had complete remissions and six (19%) had partial responses. Thus, 80% of the patients exhibited a response. Rituximab, which targets CD20, has been tested in small trials of HCL patients. In these tests, a total of 18 (30%) of 60 patients achieved complete remission. Furthermore, as we noted in our report in the *N. Engl. J. Med* article, we are unaware of any other treatment, including interferon alpha, fludarabine, chlorambucil, and multiagent chemotherapy, that can produce such a high rate of complete remission in purine analog-resistant

HCL. Complete remission can be achieved using purine analogs, however, there is a 13% to 50% incidence of minimal residual disease, defined as collections of CD20⁺ or TRAP⁺ cells in the bone marrow biopsy by immunohistochemistry. In the 19 patients that achieved complete remission with BL22, only one patient had minimal residual disease as defined by these criteria. Thus, BL22 is also capable of inducing complete remission without minimal residual disease in a high percentage of patients. In summary, although we had expected BL22 to exhibit a positive clinical effect for the treatment of HCL, we were surprised at this unprecedented high level of response in these patients.

Dated: _____

4/24/08


Robert J. Kreitman, M.D.

Appendix A to Declaration

CURRICULUM VITAE

Name: Robert J. Kreitman, M.D.

Date and Place of Birth: November 11, 1959; Columbus, OH

Citizenship: United States

Marital Status: Married, three children

Education and Training:

September 1978-May 1981-- Bachelor of Science
Kent State University
Kent, Ohio
Majors: Chemistry and Pre-Medicine

September 1981-June 1985-- Doctor of Medicine
Ohio State University College of Medicine
Columbus, Ohio

July 1985-June 1988-- Internal Medicine Residency
Duke University Medical Center
Durham, North Carolina

July 1988-June 1991 Medical Oncology Fellowship
National Cancer Institute
Bethesda, Maryland

Board Certification:

1983-1985 National Medical Boards, Parts I-III

1988 Internal Medicine Boards

1991 Medical Oncology Boards

2001 Recertified, Medical Oncology Boards

Brief Chronology of Employment:

July 1985-June 1988 Internal Medicine Residency, Duke University
Medical Center, Durham, North Carolina

July 1988-June 1991	Medical Oncology Fellowship, National Cancer Institute (NCI), Bethesda, MD
July 1988-October 1989	Medical Staff Fellow, NCI (Civil Service)
October 1989 - June 1992	Clinical Associate, NCI, NIH, United States Public Health Service (USPHS)
July 1992 - May 1994	Senior Clinical Investigator, NCI (USPHS)
May 1994-June 2000	Lead Clinical investigator, Tenured member, NCI (USPHS)
June 2000-present	Chief, Clinical Immunotherapy Section, Laboratory of Molecular Biology, NCI (USPHS)
Current Rank	Captain (Temp O6, Perm O6), USPHS

Short Biography:

Dr. Kreitman received his M.D. from Ohio State University in 1985 and training in Internal Medicine at Duke University Medical Center from 1985 to 1988. He completed a fellowship in Medical Oncology at the National Institutes of Health, where he has remained working in the development of new recombinant biologic therapy for Cancer. He now is Chief of the Clinical Immunotherapy Section of the Laboratory of Molecular Biology in the National Cancer Institute. He directs both clinical and laboratory research teams testing and developing these therapies.

Societies:

American Medical Association (AMA)

Commissioned Officers Association (COA)

American Association for Cancer Research (AACR)

American Society of Hematology (ASH)

Molecular Medicine Society

American College of Physicians (ACP)

American Society of Clinical Oncology (ASCO)

Honors & Other Special Scientific Recognition:

September 1978 - May 1981:

Advanced placement credit from high school 1 1/3 years.

First Place winner of \$6000 Waldo Semon Vinyl Chemistry
Scholarship Exam

Lubrizol Chemistry Award

Graduated Magna Cum Laude with General Honors for Senior
Research Thesis

1982 Elected to Landacre Honorary Research Society

1985 Geriatric Medicine Award

1988 Case Report Award

1994 Federal Technology Transfer Award

1998 Bicentennial unit commendation, USPHS

1999 Commendation Medal, USPHS

1999 Federal Technology Transfer Award

2000 Competative Supplement Award, NIH

2000 DBS Technology Transfer Award

2001 Outstanding Service Medal, USPHS

2001-2007 Technology transfer awards

July 2007 Competative promotion to Permanent O6, USPHS.

Involvement in Clinical Trials:

1. Phase I study of anti-Tac(Fv)-PE38 (LMB-2), a recombinant single-chain immunotoxin for treatment of Tac-expressing malignancies (Principal Investigator).
2. Phase I/II study of adjuvant therapy for recurrent malignant glioma using Interleukin-4 Pseudomonas exotoxin (Associate Investigator).
3. Phase I study of BL22 recombinant immunotoxin for treatment of B-cell leukemias and lymphomas (Principal Investigator).
4. HLA-mismatched peripheral blood mobilized precursor transplantation followed by T cell add-back for high risk hematologic malignancies (Associate Investigator).
5. Phase I study of the recombinant toxin DT388-GM-CSF in patients with recurrent acute myelogenous leukemia (Associate Investigator)
6. Phase I Study of LMB-9, a Recombinant Disulfide Stabilized Immunotoxin for Advanced Carcinomas that Express Lewis Y Antigen (Principal Investigator).
7. Phase I Study of SS1(dsFv)-PE38 Anti-Mesothelin Immunotoxin in Advanced Malignancies: Continuous Infusion x 10 days (Principal Investigator).
8. Phase I Study Of BL22, A Recombinant Immunotoxin For Chronic Lymphocytic Leukemia and CD22+ Lymphomas (Principal Investigator)
9. Phase I Study of LMB-9, a Recombinant Disulfide Stabilized Anti-Lewis Y Immunotoxin Administered by 5- days Continuous Infusion for Patients with Colo-Rectal, Oesophageal, Pancreatic or Gastric carcinoma that express Lewis Y-Antigen (Co-investigator)
10. Phase II Trial of BL22 Immunotoxin in Hairy Cell Leukemia (Principal Investigator)
11. A Phase I Study of LMB-9, a Recombinant Disulfide Stabilized Anti-Lewis Y Immunotoxin Administered by 5- days Continuous Infusion for Patients with Colo-Rectal Adenocarcinoma (Collaborator)
12. A Phase II Clinical Trial of Anti-Tac(Fv)-PE38 (LMB-2) Immunotoxin for Treatment of CD25 Positive Cutaneous T-Cell Lymphomas (Principal Investigator)

13. Pediatric Phase I Trial of LMB-2 for Refractory CD25-Positive Leukemias and Lymphomas (Associate Investigator)
14. Pediatric Phase I Trial of BL22 for Refractory CD22-Positive Leukemias and Lymphomas (Associate Investigator)
15. Hematologic Malignancy Biology Study (Associate Investigator)
16. A Pilot Clinical Trial of Anti-Tac(Fv)-PE38 (LMB-2) Immunotoxin for Treatment of CD25 Positive Hodgkin's Disease after Fludarabine and Cyclophosphamide. (Principal Investigator)
17. A Phase II Clinical Trial of Anti-Tac(Fv)-PE38 (LMB-2) Immunotoxin for CD25 Positive Hairy Cell Leukemia (Principal Investigator)
18. A Phase 1, Multicenter, Dose Escalation Study of CAT-8015 in Patients with Relapsed or Refractory Hairy Cell Leukemia (HCL) (Principal Investigator)
19. A Phase 1, Multicenter, Dose Escalation Study of CAT-8015 in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL), Prolymphocytic Leukemia (PLL), or Small Lymphocytic Lymphoma (SLL) (Principal Investigator)
20. A Phase 1, Multicenter, Dose Escalation Study of CAT-8015 in Patients with Relapsed or Refractory Non-Hodgkin's Lymphoma (NHL) (Principal Investigator)
21. Extended Access Protocol of CAT-3888 Immunotherapy in Relapsed or Refractory Hairy Cell Leukemia (HCL) Patients who have Previously Received Pseudomonas-Exotoxin Immunotoxins (Principal Investigator)
22. Pilot Trial of LMB-2 after Fludarabine and Cyclophosphamide for CD25 Positive Lymphoid Malignancies (Principal Investigator)

Grant review experience:

1. Department of Energy Study Section, 1994.
2. American Cancer Society Study Section, 1995.
3. Department of Energy Individual Grant Review, May, 1997.

4. Department of Energy Individual Grant Review, December, 1997.
5. United States-Israel Binational Science Foundation, May, 1999
6. Leukemia Busters grant, Fall, 2007

Invited Talks:

Fifth International Conference on Immunopharmacology
Tampa, Florida, May, 1991

Experimental Pharmacology Meeting
Orlando, Florida, 1992

Gordon Conference, Tilden, New Hampshire,

Lilly Oncology Global Medical Conference
Indianapolis, Indiana, May, 1996

Fourth Workshop on Targeted Cancer Therapy, UICC Cancer treatment
Program, Bethesda, Maryland, August, 1996

Seminar, University of Arkansas Department of Medical Oncology,
Little Rock, Arkansas, 1996

IBC's International Conference on Novel Therapeutic Proteins for
Oncology, San Diego, California, 1998

Seminar, UCLA Departments of Medical Oncology/Urology
Los Angeles, California, July, 1998

Phase I Meeting, Gaithersburg Hilton, Gaithersburg, MD September, 1998

Lymphoma and Leukemia Interest Group Seminar, NIH, September, 1998

4th European Conference on Gene Therapy of Cancer
Milan, Italy, September, 1998

Johns Hopkins Leukemia Group, Johns Hopkins University Hospital,
October, 1998.

UICC International Conference, Bermuda, November, 1998

University of Minnesota College of Medicine, Minneapolis, MN,
December, 1998.

IBC's 9th Annual International Conference on Antibody Engineering
Conronado, California, December, 1998

CBER Seminar, FDA, January, 1999.

Cancer Center Grand Rounds, Wake Forest University School of
Medicine, Winston-Salem, NC, January, 1999.

Seminar, Cornell University Medical School Center for Lymphoma and
Leukemia, New York, NY, January, 1999.

FDA workshop on "Characterization of conjugated proteins", Mayflower
Hotel, Washington, DC, January, 1999.

Grand Rounds, NCI, Bethesda, MD, February, 1999.

Annual Meeting of the Society for Industrial Microbiology, Arlington, VA,
August, 1999.

Seminar, The Technion, Haifa, Israel, December, 1999.

Minisymposium, American Association for Cancer Research Annual
Meeting, San Francisco, April, 2000.

Discussion, American Society of Clinical Oncology Annual Meeting, New
Orleans, LA, May, 2000

Recombinant Antibodies, Baltimore, MD, June, 2000

Seminar, Washington Hospital Center, September, 2000.

NIH Director's Seminar, NIH, Bethesda, MD, December, 2000

Recombinant Antibody Conference, San Diego, CA, December, 2000

American Society of Hematology Simultaneous Session, San Francisco,
CA, December, 2000

Seminar, Department of Transfusion Medicine, NIH, January, 2001

AACR meeting, New Orleans, LA, March, 2001.

AACR press conference on highlighted abstract, New Orleans, LA, March, 2001.

ASCO meeting, San Francisco, CA, May, 2001.

International Conference on B Cell Lymphoproliferative Disorders,
Amsterdam, The Netherlands, June, 2001.

Bench to Bedside Talk, NIH, June, 2001.

IBC conference, Munich, GE, July, 2001.

Biopharmaceutical Development Program Retreat, Frederick, MD,
August, 2001

Sixth International Symposium, Biologic Therapy of Cancer, Munich, GE,
September, 2001.

IBC conference, San Diego, December, 2002.

Foundation for Promotion of Cancer Research, 15th International
Symposium, Tokyo, Japan, January 17, 2002

Seminar, Washington Hospital Center, Washington, DC, January 25, 2002

Surgery Conference, NIH, March 4, 2002.

AACR meeting, San Francisco, April 8, 2002

ASCO meeting, Orlando, May 20, 2002

1st International Congress on Targeted Therapies in Cancer, Washington,
DC, August 18, 2002.

2nd International Congress on Monoclonal Antiodies in Cancer, Bamff,
Alberta, Canada, August 29, 2002.

Global Organization against Leukemia - Leukemia 2002, Miami, FL,
September 19, 2002.

Keynote Speaker, 18th Annual Medical School Research Day, Wake Forest University Medical School, Winston-Salem, NC, October 2, 2002.

Pediatric Oncology Branch Seminar, December 13, 2002.

Grand Rounds, Washington Hospital Center, Washington DC, March 17, 2002.

M.D. Anderson Seminar, Houston, TX, May 12, 2003

Recombinant Antibody Conference, Boston, MA, May 15, 2003

Immunocytochemistry Meeting, Phoenix, AR, May 29, 2003

Seminar, Dept. of Transfusion Medicine, NIH, January 23, 2004.

IBC conference on Recobminant Antibodies, Munich, Germany, May 19, 2004.

Seminar, Medical Oncology Clinical Research Unit, NCI, May 21, 2004.

4th International Congress on Monoclonal Antibodies, Colorado Springs, Sept. 6, 2004.

Talk on BL22 at Genecor International, San Franscisco, CA, October 12, 2004.

Talk, Genencor International, San Franscisco, CA, July 9, 2005.

Talk for Dinisco/Cambridge Antibody Technology, Bethesda, October 19, 2005.

IBC conference, London, March 15, 2006

Talk for Targeted Tumor Therapies Conference, Berlin, March 30, 2006.

AACR annual meeting, minisymposium, Washington, DC, April 5, 2006.

Cambridge Antibody Technologies Expert's meeting on SS1P, October 18, 2006.

American Cancer Society Meeting, Albuquerque, NM, November 1, 2006.

Department of Transfusion Medicine Seminar, February 23, 2007.

Grand Rounds, Washington Hospital Center, September 7, 2007.

Annual Bertha Bouroncle honorary lecture, Ohio State Univ., May, 2008.

Editorial Board:

1. Oncology Reports
2. Current Molecular Medicine
3. Section Editor/ Advisory board for Expert Opinion on Biological Therapy
4. Editorial Advisory Board member for Current Molecular Medicine

Patents

1. Circularly permuted IL4 toxin.
2. Recombinant Immunotoxin BL22
3. Improved version of LMB-2 immunotoxin with reduced toxicity
4. Improved version of BL22 with increased affinity
5. Assay for soluble CD22 for measuring tumor burden in B-cell lymphomas.
6. PEGylation of linkers to improve antitumor activity and reduce toxicity of immunoconjugates.
7. Mutated Pseudomonas exotoxins with reduced antigenicity
8. Anti-CD30 antibodies suitable for immunotoxins

Special panels

1. Ricin Toxin Expert Panel Workshop held in Bethesda, MD on April 1 - 2, 2004.

Research Interests

1. Clinical development of recombinant anti-CD22 immunotoxins in patients with hematologic B-cell malignancies.
2. Clinical development of recombinant anti-CD25 immunotoxin in patients with hematologic malignancies.
3. Characterization of hairy cell leukemia with respect to normal T-cell and B-cell repertoire, and immunoglobulin recombinations expressed by the leukemic cells.
4. Development of a high sensitivity clone-specific PCR assay for minimal residual disease in hairy cell leukemia.
5. Development of soluble CD22 as a marker for B-cell malignancies.
6. Study of the renal excretion of recombinant immunotoxins in patients, and study of the mechanisms of hemolytic uremic syndrome in patients treated with recombinant immunotoxin BL22.

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BIBLIOGRAPHY

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2. Siegall, C.B., Kreitman, R.J., FitzGerald, D.J., and Pastan, I.: Antitumor effects of interleukin 6-*Pseudomonas* exotoxin chimeric molecules against the human hepatocellular carcinoma, PLC/PRF/5 in mice. *Cancer Res.* 51: 2831-2836, 1991.
3. Kreitman, R.J., FitzGerald, D., and Pastan, I.: Targeting growth factor receptors with fusion toxins. *Int. J. Immunopharmac.* 14: 465-472, 1992.
4. Kreitman, R.J., Chaudhary, V.K., Siegall, C.B., FitzGerald, D.J., and Pastan, I.: Rational design of a chimeric toxin: an intramolecular location for the insertion of transforming growth factor α within *Pseudomonas* exotoxin as a targeting ligand. *Bioconjug. Chem.* 3: 58-62, 1992.
5. Kreitman, R.J., Siegall, C.B., Chaudhary, V.K., FitzGerald, D.J., and Pastan, I.: Properties of chimeric toxins with two recognition domains: interleukin 6 and transforming growth factor α at different locations in *Pseudomonas* exotoxin. *Bioconjug. Chem.* 3: 63-68, 1992.
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14. Mesri, E.A., Kreitman, R.J., Fu, Y.-m., Epstein, S.E., and Pastan, I.: Heparin-binding transforming growth factor α -*Pseudomonas* exotoxin A. *J. Biol. Chem.* 268: 4853-4862, 1993.
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19. Kreitman, R.J., and Pastan, I.: Purification and characterization of IL6-PE^{4E}, a recombinant fusion of interleukin 6 with *Pseudomonas* exotoxin. *Bioconjug. Chem.* 4: 581-585, 1993.
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 26. Kreitman, R.J., Chang, C.N., Hudson, D.V., Queen, C., Bailon, P., and Pastan, I.: Anti-Tac(Fab)-PE40, a recombinant double-chain immunotoxin which kills interleukin-2-receptor-bearing cells and induces complete remission in an *in vivo* tumor model. *Int. J. Cancer* 57: 856-864, 1994.
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 28. Kreitman, R.J., Puri, R.K., and Pastan, I.: A circularly permuted recombinant interleukin 4 toxin with increased activity. *Proc. Natl. Acad. Sci. USA* 91: 6889-6893, 1994.
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